Continuous and Bi-level positive airway pressure for motion mitigation of intra-thoracic tumors treated with radiotherapy

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The main objective of this pilot study is to evaluate the effect of motion mitigation with BiPAP or CPAP on tumor motion during the course of radiotherapy in patients with intra-thoracic tumors.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON49188

Source
ToetsingOnline

Brief title
Mechanical ventilation for motion mitigation during radiotherapy.

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
esophageal cancer, lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radiotherapie (DA30)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: BiPAP, CPAP, Motion Mitigation, Radiotherapy

Outcome measures

Primary outcome

The primary endpoint is the effect of CPAP or BiPAP on tumor motion (tumor amplitude expressed in millimeters) during the course of radiotherapy.

Secondary outcome

Phase 1: Feasibility of the use of CPAP and BiPAP in terms of the time a patient can use CPAP or BiPAP. We consider it feasible in case patients can wear the mask more than 10 minutes.

Phase 2: Change in lung volumes (based on CT images); tidal volumes and breathing frequency with the use of CPAP or BiPAP in healthy controls and patients with intra-thoracic tumors. Feasibility of CPAP or BiPAP use for patients with intra-thoracic tumors. To evaluate this, the duration of wearing the mask will be monitored. We consider it feasible in case patients can wear the mask more than 10 minutes. Reproducibility of controlling lung volumes during the course of radiotherapy by evaluation of the base-line shift. The influence of the anticipated reduction in target volume and the consequences for the dose distributions (to the target and to the organs at risk) for both photon and proton based radiotherapy plans (with and without mechanical

ventilation).

Study description

Background summary

Compared to photon radiotherapy, radiotherapy using protons may reduce toxicity in patients with intra-thoracic tumors. However, breathing motion of intra-thoracic tumors is a concern for proton therapy as tumor motion may increase dose uncertainty substantially. Although sophisticated radiotherapy planning techniques have been developed to take these uncertainties into account, motion mitigation may still be beneficial, especially in target volumes that show large tumor motion. With the use of a ventilator that is able to regulate and modulate the breathing pattern of the patient, this reduction in tumor motion may be achieved. In turn, this may result in a more robust proton treatment plan.

Study objective

The main objective of this pilot study is to evaluate the effect of motion mitigation with BiPAP or CPAP on tumor motion during the course of radiotherapy in patients with intra-thoracic tumors.

Study design

The study will follow a 2-step approach. First we will investigate the feasibility of short-term use of CPAP and BiPAP and its effects on lung volumes, tidal volumes and breathing frequency in patients with cancer who are planned for thoracic radiotherapy. By doing so we are able to select the best setting of BiPAP/CPAP with which minimal tumor motion is expected. In a second phase we will investigate this particular setting of BiPAP or CPAP in the setting of radiotherapy: weekly repeated CTs will be acquired during the course of radiotherapy to evaluate the effect of BiPAP and CPAP on tumor motion and its consequential effects on target coverage of the radiotherapy treatment plan.
Phase 1: initially 10 patients (5 with lung cancer and 5 patients with esophageal cancer or malignant lymphoma) will be included to refine the ventilatory assist protocol prior to radiotherapy. Changes in lung volumes compared to spontaneous breathing will be measured using electrical impedance tomography (EIT). Furthermore, we will monitor the participant for comfort and safety.
Phase 2: the optimal assists mode (CPAP or BiPAP) will be incorporated in the routine preparations for radiotherapy for intra-thoracic tumors. Patients will be treated according to standard clinical practice. Study participants will

undergo extra repeated 4D-CTs (without contrast agent, while on BiPAP or CPAP using optimal assist mode) once every week during treatment.

Study burden and risks

Participation in this study does not involve any additional risk to healthy subjects nor patients, besides the risk incurred by additional CT-scans for the patients. CPAP or BIPAP for short periods is not associated with risks.
Patients will undergo weekly repeated CTs during the course of radiotherapy; in total this consists of a maximum of 11 extra CTs. The additional effective dose of these extra images is low (i.e., 11 x 25-30mSv for the 4DCTs, resulting in a total extra dose < 330mSv) compared to the radiation dose of the treatment (20 - 60Gy). The risks are therefore negligible and the burden is low. No extra hospital visits are necessary as the appointments for the repeated 4D-CTs are scheduled together with the regular visits during the course of radiotherapy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Intra-thoracic malignancy (locoregionally advanced stage lung cancer, esophageal cancer or malignant lymphoma) that wil be treated with curative intent with radiotherapy. Informed consent needs te bo obtained. Age: 18 years or older.

Exclusion criteria

- Facial deformations so that facial mask are impossible to fit
- Noncompliance with any of the inclusion criteria.
- Planned for radiotherapy with fraction dose >=3 Gy.
- Severe heart failure (LVEF<30%)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-06-2021
Enrollment:	31
Type:	Actual

Medical products/devices used

Generic name:	CPAP/BiPap ventilator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-07-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL71871.042.19